INTRODUCTION

The present invention relates to the modification of rapid tests, such as immunochromatographic tests, presently used to diagnose such diseases as otitis media and pneumococcal pneumonia, to reduce the incidence in children particularly of false positive results attributable to nasopharyngeal colonization of otherwise healthy individuals by the same bacteria that are responsible for otitis media and either pneumococcal pneumonia *per se* or other respiratory ~~pneumonic~~ diseases clinically indistinguishable therefrom.

BACKGROUND OF THE INVENTION

Pneumonic disease and otitis media, especially in children up to the age of about 12 years, represent a serious global health problem which is aggravated by the ever-growing ability of bacteria to mutate into forms that are increasingly resistant to the therapeutic effect of the various antibiotics which are the most effective medications against them. In the United States alone, approximately 4.3 million cases of pneumonia occur in persons of all ages annually and about half of them are caused by bacteria. About 2.5 million visits to physicians are made in the U.S. for the purpose of seeking treatments for otitis media--again about 50% attributable to bacteria. Otitis media is known to be largely a disease of young children.

It has been estimated that about 4 million children throughout the world die annually from acute respiratory diseases, preponderantly in developing countries. Studies show that

assay in urine, *Chest* 2001, vol. *119*, 243-9; Yu V.L., Kellog, J.A, Plouffe, J.F. *et al*, Evaluation of the Binax Urinary, Gram stain and sputum culture for *Streptococcus pneumoniae* in patients with community-acquired pneumonia, 38th Annual Meeting of the Infectious Disease Society of America, New Orleans, LA, Abstract #262 (2001).

The NOW® bioassay is described and claimed in co-pending, commonly assigned U.S. Patent Application Serial No. 09/397,110 ~~09/399,710~~ filed September 16, 1999, which is incorporated herein by reference and also its parent application Serial No. 09/156,486 filed September 18, 1998 and now abandoned.

A study of pneumonia conducted in China found that children with nasopharyngeal carriage of *Streptococcus pneumoniae* had high rates of positive urine results in the NOW® test even when they had no pneumonic disease and that the test results accordingly did not fit the sensitivity and specificity profile established with adult subjects. A study in Gambia found that 87% of well children tested were nasopharyngeal carriers of *Streptococcus pneumoniae* and that 55% of these, or about 47% of this population, gave false positive results in the Binax NOW® test. See Adegbola, R.A., Obaro, S.K., Biney, E. and Greenwood, B.M., Evaluation of Binax NOW ® *Streptococcus pneumoniae* urinary antigen test in children in a community with a high carriage rate of pneumococcus, Pediatr. Infect. Dis. J. 2001, July; 20 (7) 718-719. See also Dowell, S.F., Garman, R.L., Liu, G., Levine, O.S. and Yang, Y.H., Evaluation of Binax NOW as assay for the detection of pneumococcal antigen in urine samples performed among pediatric patients, Clin Infect Dis. J. 2001, vol. *32*, 824-825 (2001). A similar study conducted among 210 children in Quito, Ecuador, confirmed that urine from children with nasopharyngeal carriage of *Streptococcus pneumoniae* gives a high proportion of false positive